ENVIRONMENTAL WORKING GROUP

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June 14, 2004

Documents Management Branch
Food and Drug Administration
Department of Health and Human Services, Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

RE: *EWG COSMETICS PETITION*

Dear Sir or Madam,

Environmental Working Group submits the attached petition regarding potential violations of cosmetics safety regulations. Enclosed, you will find four copies of the petition and supporting documents. Please accept this petition the and accompanying exhibits for your consideration.

Please contact Arianne Callender or Jane Houlihan at (202) 667-6982 for any questions or concerns regarding the petition.

Sincerely,

Arianne Callender

Arianne Callender
General Counsel

enc (5)

cc:

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

2004P-0266

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CITIZEN PETITION TO CEASE UNLAWFUL SALE OF MISBRANDED & ADULTERATED COSMETICS

To secure the safety of the millions of consumers who use personal care products in their daily lives, Environmental Working Group (EWG) petitions the Food and Drug Administration (FDA) to take immediate action to cease the unlawful distribution of misbranded, adulterated and unlabeled cosmetics. American consumers rely upon the Food and Drug Administration for protection from exposure to unsafe food, drug and cosmetic products. Armed with the authority of the Food Drug and Cosmetic Act (FD&CA), the FDA is charged with the duty of ensuring the safety of cosmetic products available to consumers. Based on an in-depth investigation of over 10,000 personal care product ingredients, Environmental Working Group has identified serious probable safety violations of the FD&CA by cosmetics manufacturers and retailers, and submits this petition seeking the following enforcement actions by the Commissioner of Food and Drugs:

(1) Institute a voluntary recall or court-ordered injunction or seizure for cosmetics containing ingredients that have not been proven safe through scientific testing that do not bear appropriate warnings, pursuant to 21 U.S.C.A. § 362, 21 U.S.C.A. § 332, 21 U.S.C.A. § 334, 21 C.F.R. § 7.40, and 21 C.F.R. § 7.45 ;

(2) Clarify the requirements for adequate substantiation of safety, pursuant to 21 U.S.C.A. § 371(a), 21 C.F.R. § 740.10(a);

(3) Establish a requirement that manufacturers remove from cosmetic products any ingredient that contains any toxic impurity or that may combine with other ingredients to form harmful impurities, pursuant to 21 U.S.C.A. § 371(a);

(4) Initiate a voluntary recall or court-ordered injunction or seizure for cosmetics containing ingredients that may cause injury through ordinary use, pursuant to 21 U.S.C.A. § 361, 21 U.S.C.A. § 332, 21 U.S.C.A. § 334, 21 C.F.R. § 7.40, and 21 C.F.R. § 7.45;

(5) Publicly command all Internet vendors to display a conspicuous list of ingredients of cosmetic products sold on their websites, subject to injunction or seizure, pursuant to 21 C.F.R. § 701.3, 21 C.F.R. § 701.2, 21 U.S.C.A. § 362, 21 U.S.C.A. § 375, and 21 U.S.C.A. § 336; and

(6) Conduct an investigation of products containing chemical ingredients prioritized according to prevalence and toxicity, pursuant to 21 U.S.C.A. § 372, and 21 U.S.C.A. § 374.

COSMETICS SAFETY CONCERNS CONFRONT MILLIONS ON A DAILY BASIS

Americans are exposed to 126 different cosmetic chemicals daily. Cosmetics use, which supports this $35 billion industry, poses serious safety concerns for a broad cross-section of the population. A cosmetic is defined in the FD&CA as an article, or component thereof, which is "intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance." *See* 21 U.S.C.A. 321 (I). EWG conducted a survey of 2,300 people, which shows that the average adult uses 9 cosmetic products each day, with 126 unique chemical ingredients. *See* Environmental Working Group, *Skin Deep* (June 7, 2004), http://www.ewg.org/reports/skindeep (hereinafter "*Skin Deep*")(attached as Exhibit E). More than a quarter of all women and one of every 100 men use at

least 15 cosmetic products daily. *See id.* Despite this population-wide exposure to cosmetic chemicals, the existing law governing cosmetics has cast a disturbingly narrow safety net.

89% of the 10,500 personal care product ingredients remain untested. As of the end of 2003, the CIR had reviewed 1,175 cosmetic ingredients, just 11 per cent of the 10,500 ingredients used in personal care products according to FDA statistics. *See* Cosmetics Toiletry and Fragrance Association, *Product information: 2004 CIR Compendium* (CTFA 2004), www.ctfa.org (visited May 6 2004), *see also* Food Drug Administration Center for Food Safety and Applied Nutrition, *Cosmetics Compliance Program, Domestic Cosmetics Program*, Ch. 29 - Cosmetics and Color Technology 2000 (July 31, 2000), http://vm.cfsan.fda.gov/~comm/cp29001.html (visited May 10, 2004). Of the 7,500 products that EWG analyzed, just 28 have been fully assessed for safety by the cosmetic industry's review panel. All other products — 99.6 percent of those examined — contain one or more ingredients that have never undergone a public safety review. *See Skin Deep*. According to FDA's Office of Cosmetics and Colors, "a cosmetic manufacturer may use almost any raw material as a cosmetic ingredient and market the product without an approval from FDA." FDA *Diethalonomine and Cosmetic Products. Office of Cosmetics and Colors Fact Sheet*, 1999, http://vm.cfsan.fda.gov/~dms/cos-dea.html (visited May 6, 2004).

A self-regulating industry panel is the only existing safety screen for cosmetics. Because the FDA lacks authority to require pre-market safety assessments of cosmetics, the responsibility for ingredients safety review rests largely in the hands of the cosmetic industry's self-regulating panel, the Cosmetic Ingredient Review (CIR). No other independent authority exists that is charged with the review of cosmetic safety. Manufacturers may conduct their own testing, but this testing is not required to be made public or to be reported to the FDA.

The CIR was established in 1976 as a joint effort between the Cosmetic, Toiletry and Fragrance Association (CTFA), the FDA and the Consumer Federation of America (CFA). FDA sits on the panel as a non-voting member along with the other two founding organizations. *See* CIR website, http://www.cir-safety.org (visited May 18, 2004). Voting members are nominated by the three non-voting founding organizations, and are selected from the medical and scientific community. *See id.* In analyzing a particular ingredient, CIR will conduct a review of scientific literature, provide for public comment, conduct public discussions of the panel's findings, and issue a final report in a peer-reviewed scientific journal. *See id.* The panel may direct industry to conduct studies or release unpublished data if existing scientific literature on the safety of ingredients is insufficient. *See id.* While CIR findings are not binding on FDA, FDA has historically relied upon CIR's conclusions in making cosmetic safety rulings.[1] *See, e.g.,* Alpha Hydroxy Acid Guidance, 67 FR 71577.

In light of these safety considerations, it is of the utmost importance that FDA exercise its authority to the fullest extent possible to preserve the safety of American consumers.

EWG INVESTIGATION REVEALS ACTIONABLE VIOLATIONS OF FDA SAFETY LAWS

EWG has conducted an investigation of more than 10,000 personal care product ingredients, which has revealed serious violations of FDA's consumer safety standards. EWG's analysis compares ingredients in 7,500 personal care products against lists of known and suspected chemical health hazards produced by government agencies such as the FDA, EPA and CDC, industry organizations such as the Cosmetics Industry Review Panel (CIR), and academics published in peer-reviewed journals.

[1] In a May 18, 2004 conversation with FDA Compliance Officer, Lark Lambert, Lambert stated that there has been no divergence between the panel's findings and the agency's rulings in the 28 years since CIR's inception.

Through this process, serious violations of the FD&CA have been brought to our attention:

1. EWG has identified 356 cosmetic products containing ingredients that may not have been proven safe, and fail to bear the required warning. *See* Exhibit A. These products may be misbranded and subject to voluntary recall, injunction or seizure. *See* 21 U.S.C.A. § 362, 21 U.S.C.A. § 332, 21 U.S.C.A. § 334, 21 C.F.R. § 7.40, and 21 C.F.R. § 7.45.

2. EWG has discovered 20 cosmetic products containing ingredients that may cause harm when used according to package directions. *See* Exhibit B. These products may be adulterated and subject to voluntary recall, injunction or seizure. *See* 21 U.S.C.A. § 361, 21 U.S.C.A. § 375, 21 U.S.C.A. § 336, and 21 C.F.R. § 701.3(b).

3. EWG has visited 41 websites offering cosmetic products for sale without conspicuously listing the ingredients. *See* Exhibit C. These websites may be selling misbranded products in violation of labeling requirements, and should be publicly notified of the violation and warned of potential injunction or seizure in the event of continued noncompliance. *See* 21 U.S.C.A. § 362, 21 U.S.C.A. § 375, 21 U.S.C.A. § 336, and 21 C.F.R. § 701.3, 21 C.F.R. § 701.2.

4. EWG has developed a list of 9 toxic cosmetic ingredients, which are widely used and pose a serious threat of injury. *See* Exhibit D. Products containing these ingredients may be misbranded or adulterated, and are subject to FDA inspection, safety review, and enforcement action where warranted. *See* 21 U.S.C.A. § 372, and 21 U.S.C.A. § 374, 21 U.S.C.A. § 361, and 21 U.S.C.A. § 362.

FACTUAL AND LEGAL SUPPORT FOR ACTION REQUESTED

1. EWG Calls Upon the Commissioner of Food and Drugs to Institute Recall, Injunction or Seizure Proceedings for Cosmetics That Have Not Been Proven Safe.

EWG has identified 356 cosmetic products which may not have not been adequately substantiated for safety and do not bear the required warning. For all of the products listed in Exhibit A, the CIR has formally concluded that at least one component ingredient has insufficient testing data to support the ingredients' safe use in cosmetics. *See* Exhibit A. According to the FD&CA, a product is misbranded if its labeling is false or misleading or if:

> any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

21 U.S.C.A. § 362(a), (c). The implementing regulations require the placement of a warning label on cosmetic products for which adequate substantiation of safety has not been obtained. *See* 21 C.F.R. 740.10(a). The regulation provides as follows:

> Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:
> Warning -- The safety of this product has not been determined.

Id. None of the 356 cosmetic products that EWG identified bear the warning required by the FDA regulations. As such, these products may be misbranded, and should be removed from the

marketplace until they are either proven safe, repackaged according to FD&CA standards or reformulated.

The Commissioner of Food and Drugs has the authority to institute recall, injunction or seizure proceedings to prosecute violations of the prohibition against misbranding. *See* 21 U.S.C.A. § 332, 21 U.S.C.A. § 334, 21 C.F.R. § 7.40, 21 C.F.R. § 7.45. In the case of a recall, the Commissioner may request a cosmetic firm to initiate a recall if a product presents a risk of illness, injury or gross consumer deception, and a recall is necessary to protect the public health and welfare. *See* 21 C.F.R. § 7.45. Cosmetics with ingredients that are inadequately substantiated for safety clearly meet this standard. As to risk of illness or injury, the fact that the CIR found that there is not sufficient data to show that the chemicals are safe for cosmetic use shows that there is potential for illness or injury to the consumer. In terms of consumer deception, FDA's labeling requirement creates a reasonable basis for a consumer to believe that the absence of a label indicates that no ingredients with unproven safety are present in a given cosmetic product. Thus, where the industry's own review panel has determined that the cosmetics are not sufficiently tested to meet this standard, the consumer has been misled by the absence of the label. An injunction may be sought to restrain any violation of the Act. *See* 21 U.S.C.A. § 332. An injunction is appropriate because the 356 products that EWG has identified fail to include the required warning. A seizure may be sought when a misbranded cosmetic has entered into interstate commerce. *See* 21 U.S.C.A. § 334. Seizure would be proper because all of the products identified by EWG are available for sale either on the Internet or in stores throughout the United States.

The only way to prevent the risk of injury, illness or consumer deception is to prohibit the continued distribution of misbranded products until the cosmetic firms either prove the safety of the ingredients, include the required warning label, or reformulate the product to remove all ingredients which have not been proven safe for use in cosmetics. EWG therefore requests that the Commissioner institute recall, injunction or seizure proceedings for the cosmetics detailed in Exhibit A.

2. EWG Calls Upon the Commissioner of Food and Drugs to Clarify the Requirements for Adequate Substantiation of Safety for the Purposes of the Labeling Provision in 21 C.F.R. § 740.10(a).

FDA's current regulations do not sufficiently explain requirements for substantiating the safety of cosmetics. *See* 21 C.F.R. § 740.10(a). The FDA has "broad statutory authority to protect the public health by 'making such rules and regulations as may be necessary to carry out the provisions of the (Federal Food, Drug and Cosmetic Act) of 1938, 21 U.S.C.A. § 301 et seq. (1976)).'" *See* Pharmaceutical Manufacturers Association v. Food and Drug Administration, 634 F.2d 106, 108 (D. Del. 1980) *quoting* Mourning v. Family Publications Service, Inc., 411 U.S. 356, 369 (1973), *see also* 21 U.S.C.A. § 371(a). While the FDA regulations require that each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing, no specific details are included to explain the meaning of the phrase "adequately substantiated for safety." The Act and its implementing regulations are completely silent on the definition of the phrase as well as the terms "substantiated" and "safety," as they apply to cosmetics.

The safety net cast by the government's oversight of cosmetics is disturbingly narrow. FDA's want of authority to require pre-market safety review makes cosmetics the least regulated industry under the agency's protection. For instance, in regulating pesticides in food, the FDA defines "safety" as "reasonable certainty of no harm from aggregate exposures ... including all anticipated dietary exposures and all other exposures for which there is reliable information," and calls for an

assessment of safety for vulnerable populations such as infants and children. 21 U.S.C.A. § 346 (b)(2)(A)(ii) & (b)(2)(C). In the cosmetics regulations, FDA has provided no guidance on the meaning of the term "safety." From a health perspective, there is no logical reason why cosmetics shouldn't meet the same standard as food.

The average adult uses nine cosmetic products each day, and many of these products are formulated with penetration enhancers that increase the delivery of component chemicals to the bloodstream. Furthermore, the industry safety review panel has identified potential hazardous impurities for about one of every ten ingredients assessed. *See* Cosmetics Ingredient Review, 2003 (hereinafter "CIR 2003"). Of the four product concerns for which FDA explicitly requests direct contact from imported cosmetic inspectors, three are related to harmful impurities in the products. *See* Center for Food Safety and Applied Nutrition Cosmetics Compliance Program—Imported Cosmetics Program, December 8, 2000, at Chapter 29—Cosmetics and Color Technology, http://vm.cfsan.fda.gov/~comm/cp29002.html (visited May 12, 2004) (hereinafter "CFSAN 2000").

While the cosmetics industry has created a self-regulating ingredient review panel, the marketplace still includes thousands of cosmetic ingredients that have never undergone a public safety review. How can a regulatory agency continue to allow such a serious breach of safety to persist?

FDA must clarify the meaning of its requirement that ingredients and finished products be "adequately substantiated for safety" to ensure the safety of cosmetics and the consumers who use them. EWG has investigated 7,500 products, not one of which bears a warning stating: "the safety of this product has not been determined." Only 28 of these 7,500 products have been fully reviewed for safety by CIR or FDA; all other products contain at least one ingredient not assessed for safety. The CIR did conduct a review of the ingredients in the 356 likely misbranded products identified by EWG, but none of these products bore the appropriate label either. These incongruities are cause for concern.

The efficacy of FDA's regulatory scheme must be revisited. Without a clear standard, FDA's enforcement and cosmetic industry's compliance efforts are undermined. Most significantly, the lack of a definitive safety standard leaves consumers without a basis for confidence in the safety of the overwhelming majority of cosmetic products. Under the current standard, a cosmetic firm could conduct unreliable tests, or even no tests at all, and still place an unsafe product on drugstore shelves without having to include a warning label or face FDA enforcement. The effect of this safety gap is that consumers will be exposed to untested chemicals that can cause serious harm, such as reproductive abnormalities or cancer. Consumers should not have to bear the burden of the government's poorly defined safety scheme.

It is imperative that FDA exercise its authority to ensure that such an unjust burden is not placed on consumers, and clarify its cosmetic safety standard to offer the greatest possible consumer protection. EWG proposes that FDA define "adequately substantiated for safety" as follows:

> *Substantiation, through peer-reviewed scientific publications or publicly available industry studies, of a reasonable certainty of no harm from aggregate exposures to the product and its component ingredients including impurities, taking into account chemicals that may increase penetration of the product or its component chemicals through the skin, and including all anticipated cosmetic exposures and all other exposures for which there is reliable information, taking into consideration vulnerable populations such as infants and pregnant women.*
>
> *Any finding of safety for a cosmetic product must explicitly account for risks posed by impurities until such time as impurities are removed from the component ingredients or the product is*

reformulated in such a way as to preclude the formation of impurities by the component ingredients in the product.

Anything less will be a disservice to the millions of Americans who rely upon the FDA to ensure the safety of cosmetic products available on the marketplace.

3. EWG Calls Upon the Commissioner of Food and Drugs to Establish a Requirement that Manufacturers Remove from Cosmetic Products any Ingredient that Contains any Toxic Impurity or that May Combine with Other Ingredients to Form Harmful Impurities.

At least 146 cosmetic ingredients have potentially hazardous impurities linked to cancer and other serious health impacts, but the FDA has not articulated any firm safety standards limiting such impurities in cosmetic products. *See* CIR 2003, CFSAN 2000, *see also* Office of Cosmetics and Colors, *Prohibited Ingredients and Related Safety Issues,* March 30 2000, http://www.cfsan.fda.gov/~dms/cos-210.html (visited May 12, 2004) (hereinafter "CFSAN 2000a"), *see also* Faust and Casserly, *Petrolatum and Regulatory Requirements,* NPRA International Lubricants & Waxes Meeting, November 13-14, 2003, Houston, TX, www.penreco.com/newsevents/tradearticles/NPRA2003_Pet_Regulations.pdf (visited May 17, 2004) (hereinafter "Faust and Casserly"), *and see* The Scientific Committee on Cosmetic and Non-Food-Products, *Opinion concerning a clarification on the formaldehyde and para-formaldehyde entry in Directive 76/768/EEC on cosmetic products,* SCCNFP/587/02 (December 17, 2002) (hereinafter "SCCNFP"), *and see EU directive on classification and labeling of dangerous substances,* Directive 67/548/EEC, Annex 1, Chemical compendium at http://europa.eu.int/comm/enterprise/chemicals/legislation/markrestr/cmrlist.pdf (hereinafter "EU 2002"). The Commissioner has the authority to issue safety standards under the FD&CA. *See* Pharmaceutical Manufacturers Association v. Food and Drug Administration, 634 F.2d 106, 108 (D. Del. 1980) *quoting* Mourning v. Family Publications Service, Inc., 411 U.S. 356, 369 (1973), *see also* 21 U.S.C.A. § 371(a). Government and industry sources reveal 24 industrial chemicals or groups of chemicals identified as potential impurities in a wide range of products, with health concerns spanning cancer, neurotoxicity, and reproductive problems. *See* CIR 2003, CFSAN 2000 & 2000a, Faust and Casserly, SCCNFP, and EU 2002. The FDA issued a recommendation to manufacturers to voluntarily remove a carcinogenic impurity, nitrosamines, from products in 1996. *See* Food and Drug Administration, *Are nitrosamines in cosmetics a health hazard?,* Office of Cosmetics and Colors, November 1996, http://vm.cfsan.fda.gov/~dms/qa-cos25.html (visited May 6, 2004). EWG proposes that FDA adopt a similar standard for all hazardous impurities:

Remove from cosmetic products any ingredient that contains any toxic impurity or that may combine with other ingredients to form harmful impurities.

FDA's regulation of these hazardous impurities will limit consumers' risk of cancer and other avoidable harm from cosmetic products.

4. EWG Calls Upon the Commissioner of Food and Drugs to Initiate Recall, Injunction or Seizure Proceedings for Cosmetics Containing Ingredients that May Cause Injury During Ordinary Use.

EWG has discovered 20 cosmetic products containing ingredients that may cause harm when used according to package directions. *See* Exhibit B. The FD&CA prohibits the distribution of cosmetics that "contain[] any ... deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under conditions of use that are customary or usual[.]" 21 U.S.C.A. § 361(a). For every product listed in Exhibit B, the CIR found that a component ingredient is not safe for the specific use indicated on the product's package directions.

Four of these products are baby products containing ingredients that the CIR determined should not be used on infant skin. These products, mostly baby skin creams and diaper rash ointments, contain directions such as "apply ointment liberally ... with each diaper change" and claims such as "especially effective as a ... barrier for Baby's diapered area." *See* Exhibit B. Thirteen of these products are acne or rash treatments, which include chemicals that the CIR has found should not be used on damaged or injured skin. *See id.* Two are face creams that include chemicals that CIR found should not be used in leave-on cosmetic products. *See id.* One is an "overnight blemish reducer" containing a chemical that the CIR determined should not contact the skin. *Id.* The instructions on this product say "cover blemishes ... once daily" and "[l]eave on overnight[.]" *Id.* All of these products appear to be in violation of the FD&CA, and are adulterated according to Section 361 of the Act. *See* 21 U.S.C.A. 361(a).

The Commissioner of Food and Drugs has the authority to institute recall, injunction or seizure proceedings to prosecute violations of the prohibition against adulterated cosmetics. *See* 21 U.S.C.A. § 332, 21 U.S.C.A. § 334, 21 C.F.R. § 7.40, 21 C.F.R. § 7.45. Cosmetics with ingredients that are unsafe for the uses indicated in the package direction meet the prerequisites for a recall as well. *See* 21 C.F.R. § 7.40, 21 C.F.R. § 7.45. As to risk of illness or injury, the fact that the CIR found that the chemicals are not safe for the marketed use proves that there is potential for illness or injury to the consumer. In terms of consumer deception, the package directions make it reasonable for a consumer to believe that the product is safe to use as directed. Thus, where the industry's own review panel has determined that a component ingredient is not safe to use in that application, the consumer has been misled into the unsafe use of a cosmetic product. In this instance, an injunction is appropriate because the 20 products that EWG has identified include ingredients that may be harmful when used according to the package directions. *See* 21 U.S.C.A. § 332. Seizure would also be proper because all of the products identified by EWG are available for sale either on the Internet or in stores throughout the United States. *See* 21 U.S.C.A. § 334.

The only way to prevent the risk of injury, illness or consumer deception is to prohibit the continued distribution of these adulterated products until the cosmetic firms either prove the safety of their products or reformulate the products to remove all unsafe ingredients. EWG therefore requests that the Commissioner institute injunction, seizure or recall proceedings for the cosmetics detailed in Exhibit B.

5. EWG Calls Upon the Commissioner of Food and Drugs to Command Internet Vendors to Display a Conspicuous List of Ingredients for Cosmetic Products Sold on Their Websites.

EWG has identified 41 websites currently selling cosmetics without displaying the ingredients, in violation of FDA ingredient listing requirements. *See* Exhibit C. Cosmetics produced or distributed for retail sale to consumers for their personal care must include an ingredient declaration. *See* 21 CFR § 701.3. The ingredient declaration must be conspicuous so that it is likely to be read at the time of purchase. *See* 21 C.F.R. § 701.2. All label statements required by regulation must be placed on the label or labeling with such prominence and conspicuousness that they are readily noticed and understood by consumers under customary conditions of purchase. *See* 21 C.F.R. § 701.2. For all of the websites listed in Exhibit C, cosmetics are offered for sale, but a listing of ingredients is not available on the website. Thus, these websites are selling cosmetics without providing a declaration of ingredients conspicuously displayed as required by FDA regulations. Under normal conditions of Internet purchase, without an on-screen display of ingredients, a consumer would have to purchase the product without having seen the required list of ingredients. This violates FDA labeling regulations, and constitutes misbranding. A product is misbranded if it fails to include required information in such a way that is likely to be understood under customary conditions of purchase. *See* 21 U.S.C.A. § 362. Thus, these websites are violating FDA regulations and appear to be selling

misbranded cosmetics.

EWG requests that the Commissioner publicly instruct all cosmetic websites to display the required declaration of ingredients, subject to injunction or seizure. The FDA has the power to seek injunction or seizure, as well as the power to issue a public notice or warning to address matters that involve gross consumer deception or FD&CA violations. *See* 21 U.S.C.A. §§ 336, 362, and 375, 21 C.F.R. §§ 701.2-701.3. The failure to provide a list of ingredients denies consumers the right to know what is in the products they are purchasing. This constitutes a violation of FDA standards as well as consumer deception. The FDA should exercise its authority to ensure that consumers have equal access to cosmetic labels both in stores and on the Internet. The regulations apply equally to all products, and Internet cosmetic vendors should be required to comply accordingly. EWG requests that FDA publicly command Internet vendors to display the required ingredient declaration on all cosmetic products, subject to further prosecution by the Commissioner in the case of continued noncompliance.

6. EWG Calls Upon the Commissioner of Food and Drugs to Conduct an Investigation of Products Containing Toxic Chemical Ingredients, Prioritized According to Prevalence and Toxicity.

EWG has identified 9 common cosmetic ingredients, which are known to pose health hazards. *See* Exhibit D. Seven of these ingredients have not been studied by FDA or CIR. FDA has the authority to conduct investigations of cosmetic chemicals, and has done so in the past for prevalent ingredients, such as Alpha Hydroxy Acids. *See* 21 U.S.C. § 372, *see also* Alpha Hydroxy Acid Guidance, 67 FR 71577. EWG has identified ingredients which pose serious health risks, including cancer, reproductive toxicity, skin toxicity, and endocrine disruption. These toxic ingredients can be found in at least 1,950 cosmetic products. *See* Exhibit D. These products may be misbranded or adulterated according to FDA regulations. *See* 21 U.S.C.A. §§ 361-362.

In order to determine whether or not to take further action to remove these products from the market, EWG requests that FDA utilize its authority and investigate these 9 priority chemicals to determine their safety for use in cosmetics.

ENVIRONMENTAL IMPACT

No environmental impact statement is included because none is required for request.

CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully Submitted,

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Exhibit A-E